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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,261	05/10/2001	Geoffrey Goldspink	117-351	5457

7590

08/08/2002

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EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 08/08/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/852,261

Applicant(s)

GOLDSPINK ET AL.

Examiner

Christopher J. Nichols

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12.14.01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-6 and 9-11 drawn to a method of treating nerve damage comprising administering to a subject in need thereof an effective non-toxic amount of an MGF (mechano-growth factor) Insulin-like Growth Factor I (IGF-I) isoform comprising amino acid sequences encoded by nucleic acid sequences of IGF-I exons 4, 5 and 6 in the reading frame of MGF and having the ability to reduced motoneuron, classified in class 514, subclass 2 for example.
 - II. Claim 7 in part, drawn to a method for treatment of a muscle whose innervating nerve has been damaged using MGF, classified in class 514, subclass 2, for example.
 - III. Claim 7 in part, drawn to a method for treatment of a muscle whose innervating nerve has been damaged using a polynucleotide encoding MGF, classified in class 514, subclass 44, for example.
 - IV. Claim 8, drawn to a method of treatment for a target organ whose innervating nerve has been damaged using a polypeptide growth factor other than MGF, classified in class 514, subclass 2, for example.
 - V. Claim 12 drawn to a method of treatment for nerve damage with “another neurologically active agent MGF is carried out in combination with MGF” described in Claim 1, classification dependent on agent structure.

- VI. Claim 13 drawn to a kit for the treatment of nerve damage comprising: MGF IGF-1, a conduit, “a further polypeptide growth factor which prevents or diminishes degeneration”, and another “neurologically active agent”, classification dependent on agent structure.
2. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I-V are directed to methods that are distinct both physically and functionally, and are not required one for the other.
3. Invention I requires search and consideration of methods to treat nerve damage comprising administering to a subject in need thereof MGF IGF-I, which is not required by any of the other groups.
4. Invention II requires search and consideration of a method of treatment of a muscle whose innervating nerve is damaged, which is not required by any of the other groups.
5. Invention III requires search and consideration of polynucleotide administration as treatment (gene therapy), which is not required by any of the other groups.
6. Invention IV requires search and consideration of “a polypeptide growth factor other than MGF”, which is not required by any of the other groups.
7. Invention V requires search and consideration of “neurologically active agent”, which is not required by any of the other groups.
8. Inventions VI and each of I-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

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different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Invention requires active ingredients other than MGF IGF-I such as a polypeptide growth factor which prevents or diminishes degenerative and another neurologically active agent. None of the methods of I-V require administration of this multiple component composition.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Conclusion

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher J. Nichols whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
August 7, 2002

A handwritten signature in black ink, reading "Elizabeth C. Kemmerer". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

ELIZABETH KEMMERER
PRIMARY EXAMINER